State of California Department of Consumer Affairs

# Memorandum

**To:** **Members, Board of Pharmacy** Date: January 10, 2005

**From:** **Virginia Herold**

**Subject:** **Legislation Report and Action**

## 1. Board-Sponsored Legislation

At the October Board Meeting, the board approved a number of legislative proposals for sponsorship.

These legislative proposals are in Attachment 1.

## 2. Pending or Introduced Legislation Related to the Practice of Pharmacy

The Legislative Session began December 6.

In Attachment 2 are some legislative proposals that have been introduced that affect the board, patients or the practice of pharmacy. At the April Board Meeting analyses of these and other bills will be provided to the board. At this time, they are being provided for information only

# Attachment 1

## *Board Omnibus Provisions for 2005*

**Board of Pharmacy**
**2005 Omnibus Proposals**

**Section 4005 of the Business and Professions Code is amended to read:**

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; and pertaining to the sale of drugs by or through any mechanical device.
(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.
(c) ~~The board may, by rule or regulation, adopt, amend, or repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession. Every person who holds a license issued by the board shall be governed and controlled by the rules of professional conduct adopted by the board.~~
~~(d)~~ The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

**Section 4053 of the Business and Professions Code is amended to read:**

4053. (a) ~~Subdivision (a) of Section 4051 shall not apply to a veterinary food-animal drug retailer or wholesaler that employs a~~ The board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall ~~adequately safeguard and~~ protect the public health and safety in the handling, storage and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.~~, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).~~
(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.
(2) He or she shall have a minimum of one year of paid work experience, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) This section shall become operative on January 1, 2006.

(f) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

**Section 4114 of the Business and Professions Code is amended to read:**

4114. An intern pharmacist may perform any activities pertaining to the practice of pharmacy as the board may determine by regulation. Whenever in this chapter the performance of an act is restricted to a pharmacist, the act may be performed by an intern pharmacist under the direct supervision and control of a pharmacist. The pharmacist shall not supervise more than two intern pharmacist at any one time.

**Section 4115 of the Business and Professions Code is amended to read:**

4115. (a) ~~Notwithstanding any other provision of law, a~~ (1) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the ~~direct~~ immediate, personal supervision and control of~~,~~ a pharmacist.

(2) Notwithstanding paragraph (1), a pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist providing services to patients in a correctional facility or to an inpatient of a hospital.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty. ~~, nor does this section authorize the use of a pharmacy technician to perform tasks specified in subdivision (a) except under the direct supervision and control of a pharmacist.~~

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the ~~direct~~ supervision ~~and control~~ of a pharmacist. Any pharmacy that employs a pharmacy technician ~~to perform tasks specified in subdivision (a)~~ shall do so in conformity with the regulations adopted by the board ~~pursuant to this subdivision~~.

(e) ~~(1)~~ No person shall act as a pharmacy technician without first being ~~registered with~~ licensed by the board as a pharmacy technician ~~as set forth in Section 4202~~.

~~(2) The registration requirements in paragraph (1) and Section 4202 shall not apply during the first year of employment for a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.~~

(f) (1) ~~The performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist. The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician. A pharmacy technician may perform the duties, as specified in subdivision (a), only under the immediate, personal supervision and control of a pharmacist.~~ For the purposes of this chapter, "immediate, personal supervision and control" means that a ~~Any~~ pharmacist ~~responsible for a pharmacy technician~~ shall be on the premises at all times, and the pharmacy technician shall be within the pharmacist's view. ~~A pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient, or by engaging in other verification procedures that are specifically approved by board regulations.~~

(2) For the purposes of this chapter, "direct supervision and control" means a pharmacist shall be on the premises at all times. ~~This subdivision shall not apply to a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility. Notwithstanding the exemption in this subdivision, the requirements of subdivisions (a) and (b) shall apply to a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility.~~

(g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist' s responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (a) and (b) ~~and (f)~~, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task

performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).
(i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician.
(k) A pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient, or by engaging in other verification procedures that are specifically approved by board regulations.

**Section 4115.5 of the Business and Professions Code is amended to read:**

4115.5. (a) Notwithstanding any other provision of law, a pharmacy technician student may be placed in a pharmacy as a pharmacy technician trainee to complete an externship for the purpose of obtaining practical training that is required by the board as a condition of becoming ~~registered~~ licensed as a pharmacy technician. A "pharmacy technician student" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education.
(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the immediate, personal supervision and control of a pharmacist. ~~A pharmacist supervising a pharmacy technician trainee shall be on the premises and have the trainee within his or her view at any time the trainee performs the duties described in subdivision (a) of Section 4115.~~
(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.
(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations..
(4) ~~No more than one pharmacy technician trainee per pharmacist may participate in an externship as described in subdivision (a) under the immediate, personal supervision and control of that pharmacist at any time the trainee is present in the pharmacy.~~
A pharmacist may only supervise one pharmacy technician trainee at any given time.
(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.
(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no more than 120 hours.
(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 320 hours. No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy.
(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates his or her student status.

**Section 4127.5 of the Business and Professions Code is amended to read:**

4127.5. The fee for the issuance of a non-governmental license, or renewal of a license, to compound sterile drug products shall be five hundred dollars ($500) and may be increased to six hundred dollars ($600).

**Section 4202 of the Business and Professions Code is amended to read:**

4202. (a) ~~An applicant for a pharmacy technician license shall be issued a certificate of registration~~ The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a general education development equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy accredited by the American Council on Pharmaceutical Education or a school of pharmacy recognized by the board. Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician certificate of registration must be returned to the board within 15 days.

(4) Is certified by the Pharmacy Technician Certification Board.

(b) The board shall adopt regulations pursuant to this section for the licensure ~~registration~~ of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for ~~registration~~ licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure ~~registration~~, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a ~~registration~~ license issued pursuant to this section on any ground specified in Section 4301.

**Section 4205 of the Business and Professions Code is amended to read:**

4205. (a) A license issued pursuant to Section 4110, 4120, ~~4130,~~ 4160, or 4161 shall be considered a license within the meaning of Section 4141.

(b) The board may, in its discretion, issue a license to any person authorizing the sale and dispensing of hypodermic syringes and needles for animal use.~~use for animals and poultry.~~

(c) The application for a license shall be made in writing on a form to be furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of ~~this article~~ Article 9 of this chapter.

(d) A separate license shall be required for each of the premises of any person who sells or dispenses hypodermic syringes or needles at more than one location.

(e) A license shall be renewed annually and shall not be transferable.

(f) The board may deny, revoke, or suspend any license issued pursuant to this article for any violation of this chapter.

**Section 4206 of the Business and Professions Code is repealed.**

4206. ~~The rules of professional conduct adopted by the board shall be printed as a part of the application for licenses and every applicant shall subscribe thereto when making an application.~~

**Section 4315 of the Business and Professions Code is amended to read:**

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with this chapter or regulations adopted pursuant to this chapter, directing the licensee to come into compliance.

(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.

(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.

(B) Prior to or at the office conference the licensee may submit to the executive officer declarations and documents pertinent tc the subject matter of the letter of admonishment.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available ~~on the pharmacy premises~~ a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

**Section 4360 of the Business and Professions Code is amended to read:**

4360. ~~It is the intent of the Legislature that the~~ The board ~~seek ways and means to~~ shall operate a pharmacists recovery program to ~~identify and~~ rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, ~~and other drugs~~ drug use, or ~~due to~~ mental illness. The intent of the pharmacists recovery program is to return ~~, so that~~ these pharmacists and pharmacist interns ~~may be treated and returned~~ to the practice of pharmacy in a manner that will not endanger the public health and safety. ~~It is also the intent of the Legislature that the board shall implement this legislation by establishing a diversion program as a voluntary alternative to traditional disciplinary actions.~~

**Section 4361 of the Business and Professions Code is amended to read:**

4361. As used in this article:

(a) "Participant" means a pharmacist or pharmacist intern who has entered the pharmacists recovery program.
(b) "Pharmacists recovery program" means the rehabilitation program created by this article for pharmacists and pharmacist interns.

~~(a) "Diversion program" means a rehabilitation program designed and administered by a contracting Employee Assistance Program, available to the board in conjunction with, or as an alternative to, other traditional sanctions that the board may impose upon pharmacists pursuant to disciplinary actions within its jurisdiction.~~
~~(b) "Employee assistance program" means an agency or organization that provides confidential assessments and referral services for persons experiencing problems related to alcohol, drug abuse, or mental illness.~~
~~(c) "Pharmacists recovery program" or "program" means the rehabilitation program created by this article for pharmacists whose competency may be threatened or diminished due to abuse of alcohol or other drugs.~~
~~(d) "Volunteer intervenor" means a pharmacist recruited through a pharmacists' professional association who is available and trained to assist pharmacists seeking the benefits of the pharmacist's recovery program.~~

**Section 4362 of the Business and Professions Code is amended to read:**

4362. (a) A pharmacist or pharmacist intern may enter the pharmacists recovery program if:
(1) The pharmacist or pharmacist intern is referred by the board instead of or in addition to other means of disciplinary action; or,
(2) The pharmacist or pharmacist intern voluntarily elects to enter the pharmacists recovery program.
(b) A pharmacist or pharmacist intern who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board based solely on the pharmacist's or pharmacist intern's entry into the pharmacists recovery program or on information obtained from the pharmacist or pharmacist intern while participating in the program unless the pharmacist or pharmacist intern would pose a threat to the health and safety of the public. However, if the board independently receives information regarding the conduct of the pharmacist or pharmacist intern such information may serve as a basis for discipline or other enforcement action by the board.

~~The program shall fulfill two distinct functions. It shall serve as a diversion program to which the board may refer licentiates, where appropriate, instead of, or in addition to, other means of disciplinary action, and it shall be a confidential source of treatment for pharmacists who, on a~~

~~strictly voluntary basis, and without the knowledge of the board, desire to avail themselves of its services.~~

**Section 4363 of the Business and Professions Code is amended to read:**

4363. ~~The board shall administer this article, provided that the names and all identifying information pertaining to those pharmacists who voluntarily seek the services of the program, apart from the institution of any disciplinary action of the board, shall not be disclosed to the board, except as provided in Sections 4370 and 4371.~~

**Section 4364 of the Business and Professions Code is amended to read:**

4364. (a) The board shall establish criteria for the participation of pharmacists and pharmacist interns in the pharmacist recovery program.
(b) The board may deny a pharmacist or pharmacist intern who fails to meet the criteria for participation entry into the pharmacists recovery program.
(c) The establishment of criteria for participation in the pharmacists recovery program shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

**Section 4365 of the Business and Professions Code is amended to read:**

4365. The board shall contract with one or more ~~employee assistance programs~~ qualified contractors to administer the ~~pharmacists~~ pharmacists recovery program. ~~statewide. The contractor shall be selected through a competitive bid process, and the contract may be renewed annually.~~

**Section 4366 of the Business and Professions Code is amended to read:**

4366. The functions of the ~~employee assistance~~ contractor administering the pharmacists recovery program shall include, but are not limited to, the following:
(a) To evaluate those pharmacists and pharmacist interns who request participation in the program. ~~according to the guidelines prescribed by the board~~.
(b) To develop a treatment contract with each participant in the pharmacists recovery program.
~~To review and designate those treatment facilities and services to which pharmacists in the program may be referred.~~
(c) To monitor the compliance of each participant with their treatment contract.
~~To receive and review information concerning a pharmacist's or pharmacist intern's participation in the program.~~
(d) ~~To assist pharmacists' professional associations in publicizing the program.~~
~~(e)~~ To prepare reports ~~to be submitted to~~ as required by the board.
(e) To inform each participant of the procedures followed in the program.
(f) To inform each participant of their rights and responsibilities in the program.
(g) To inform each participant of the possible consequences of noncompliance with the program.

**Section 4367 of the Business and Professions Code is repealed.**

**4367.** ~~The board shall designate a program coordinator whose responsibilities shall include the following:~~
~~(a) To serve as liaison between the board and the employee assistance program.~~
~~(b) To monitor and evaluate the employee assistance program.~~
~~(c) To assist the board enforcement unit in tracking pharmacists referred to the program as part of, or alternative to, disciplinary proceedings.~~

**Section 4368 of the Business and Professions Code is repealed.**

~~4368. The board shall contract with a pharmacists' professional association with statewide representation for the following purposes:~~
~~(a) To coordinate the voluntary participation in the program.~~
~~(b) To recruit volunteer intervenors and to train them.~~
~~(c) To promote the program within the profession and to the public.~~
~~(d) To establish and maintain a 24-hour statewide toll-free telephone "hotline" service.~~
~~(e) To report to the board on these functions.~~

**Section 4369 of the Business and Professions Code is amended to read:**

4369. (a) ~~The board shall inform, in writing, each pharmacist referred to the employees assistance program as part of a board action of the procedures followed in the program, of the rights and responsibilities of the pharmacist in the program, and of the possible consequences of noncompliance with the program.~~
~~(b)~~ Any failure to comply with the ~~provisions of the~~ treatment contract, determination that the participant is failing to derive benefit from the program, or other requirements of the pharmacists recovery program may result in the termination of the pharmacist's or pharmacist intern's participation in the ~~diversion~~ pharmacists recovery program. The name and license number of a pharmacist or pharmacist intern who is terminated ~~for failure to comply with the provisions of the treatment~~ from the pharmacists recovery program and the basis for the termination shall be reported to the board.
~~(c)~~ (b) Participation in ~~a~~ the pharmacists recovery program ~~under this article~~ shall not be a defense to any disciplinary action that may be taken by the board.
(c) ~~Further, no~~ No provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from the pharmacists recovery program. ~~a program under this article.~~

**Section 4370 of the Business and Professions Code is repealed.**

4370. ~~(a) The employee assistance program shall inform, in writing, each pharmacist who voluntarily participates in the diversion program without referral by the board of the procedures followed in the program, the rights and responsibilities of the pharmacist in the program, the possible consequences of noncompliance with the program.~~
~~(b) The board shall be informed of the pharmacist's noncompliance with the treatment program if the employee assistance program determines that the pharmacist's resuming the practice of pharmacy would pose a threat to the health and safety of the public. The board shall be informed of the basis for the pharmacist's termination and of the determination that the pharmacist's resuming the practice of pharmacy would pose a threat to the health and safety of the public.~~
~~(c) Participation in a program under this article shall not be a defense to any disciplinary action that may be taken by the board. Further, no provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from a program under this article.~~

**Section 4371 of the Business and Professions Code is amended to read:**

4371. The board shall review the ~~activities of the employee assistance~~ pharmacists recovery program on a quarterly basis. As part of this evaluation, the board shall review files of all participants in the ~~diversion~~ pharmacists recovery program. ~~Names of those pharmacists who entered the program voluntarily without the knowledge of the board shall remain confidential from the board except when monitoring by the board reveals misdiagnosis, case mismanagement, or noncompliance by the participant.~~

**Section 4372 of the Business and Professions Code is amended to read:**

4372. All board records and records of the ~~employee assistance~~ pharmacists recovery program pertaining to the treatment of a pharmacist or pharmacist intern in the program shall be kept confidential and are not subject to discovery, ~~or~~ subpoena, or disclosure pursuant to Chapter 3.5 of Division 7 of the Government Code (commencing with Section 6250). However, board records and records of the ~~employee assistance~~ pharmacists recovery program may be disclosed and testimony provided in connection with participation in the pharmacists recovery program ~~pursuant to Section 4369 or 4370~~, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist or pharmacist intern was terminated from the pharmacists recovery program.

**Section 4373 of the Business and Professions Code is amended to read:**

4373. No member of the ~~board or the contracting professional association or any volunteer intervenor~~ shall be liable for any civil damages because of acts or omissions that may occur while acting in good faith pursuant to this article.

**Section 4400 of the Business and Professions Code is amended to read:**

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:
(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).
(b) The fee for a nongovernmental pharmacy ~~or medical device retailer~~ annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).
(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).
(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.
(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).
(f) The fee for a non-governmental wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).
(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).
(h) ~~The fee for application and investigation for an exemptee license under Section 4053 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars ($100).~~
(1) The fee for the application, investigation and issuance of an exemptee license pursuant to Section 4053 shall be one-hundred eighty-five dollars ($185) and may be increased to two-hundred fifty dollars ($250). If the applicant is not issued an exemptee license, the board shall refund seventy-five dollars ($75) of the fee.
(2) The fee for the annual renewal of an exemptee license shall be one-hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150).
(i) ~~The fee for an exemptee license and annual renewal under Section 4053 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred~~

~~fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).~~

(1) The fee for the application, investigation and issuance of an exemptee license for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two-hundred fifty dollars ($250). If the applicant is not issued an exemptee license, the board shall refund one-hundred dollars ($100) of the fee.

(2) The fee for the annual renewal of an exemptee license for a veterinary food-animal drug retailer shall be one-hundred fifty dollars ($150).

(j) The fee for an out-of-state drug distributor's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(l) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(m) ~~The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).~~

~~(n)~~ The fee for an intern license or extension shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(s) The fee for any applicant for a non-governmental clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a license ~~registration~~ to a pharmacy technician and a separate fee for the biennial renewal of the license ~~registration~~. The ~~registration~~ license fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

# Attachment 2

## *2005 Legislation Introduced Related to the Board or the Practice of Pharmacy*

# ASSEMBLY BILL No. 21

**Introduced by Assembly Member Levine**

December 6, 2004

An act to add Section 4069 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 21, as introduced, Levine. Pharmacists: contraceptive devices.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Under existing law, a violation of those provisions is a crime.

This bill would prohibit a pharmacist from declining to dispense a contraceptive or emergency contraceptive.

Because the bill would specify an additional requirement under the Pharmacy Law, a violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

*The people of the State of California do enact as follows:*

SECTION 1. Section 4069 is added to the Business and Professions Code, to read:

4069. Notwithstanding any other provision of law, a pharmacist shall not decline to dispense a contraceptive or an emergency contraceptive pursuant to a prescription.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

# ASSEMBLY BILL No. 71

**Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, and Pavley)**

January 3, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 71, as introduced, Frommer. Pharmaceuticals: adverse drug reactions: Office of California Drug Safety Watch.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would establish the Office of California Drug Safety Watch within the department to perform duties related to adverse drug reactions. These duties would include, among others, establishing a toll–free telephone number for the purpose of receiving reports of adverse drug reactions, establishing a Web site to provide up–to–date information to the public about adverse drug reactions, and maintaining a database of adverse drug reaction reports.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. The Legislature finds and declares all of the following:

(a) Since 1997, when the United States Food and Drug Administration (FDA) allowed drug manufacturers to advertise directly to consumers, the amount spent on advertising has risen dramatically.

(b) According to the United States General Accounting Office (GAO) report, the pharmaceutical industry spent $2.7 billion in 2001 on direct–to–consumer advertising. A December 6, 2004, New York Times report states that such spending has reached $3.8 billion.

(c) According to the same GAO report, while overall spending on drug promotion was less than spending on research and development ($19.1 billion versus $30.3 billion), spending on direct–to–consumer advertising is increasing at a faster rate than overall drug promotion spending or spending on research and development. Between 1997 and 2001, the increase in direct–to–consumer advertising was 145 percent compared to a 59 percent increase for research and development.

(d) Although the FDA is responsible for postmarket surveillance of prescription drugs, numerous concerns have been raised about the adequacy of these efforts.

(e) An unpublished internal FDA study from 2002 revealed that 18 percent of FDA scientists reported being pressured to approve a new drug "despite reservations about the safety, efficacy or quality of the drug."

(f) A 1999 FDA survey and a Kaiser Family Foundation survey both found that more than 50 million people respond to drug advertisements by asking their doctor whether the advertised medications might work for them. At the same time, both surveys showed that almost 60 percent of consumers found the side–effect warnings in these advertisements to be inadequate.

(g) Pressure to get new drugs to market, combined with the vast amount of drug marketing undertaken by manufacturers, make it difficult to address a threat once it is identified. Recent studies linking the use of popular, widely promoted prescription

drugs to serious public health concerns point to the need for greater oversight to protect the public.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Office of California Drug Safety Watch

111657. There is hereby established in the State Department of Health Services the Office of California Drug Safety Watch, which shall perform all of the following duties:

(a) Establish a toll–free telephone number for the purpose of receiving reports of adverse drug reactions.

(b) Establish a Web site to provide up–to–date information to the public about adverse drug reactions.

(c) Maintain a database of adverse drug reaction reports.

(d) Act as a liaison with all appropriate parties, including the United States Food and Drug Administration, drug manufacturers, pharmacists, physicians, health care providers, and consumer drug safety organizations, to ensure the speedy and accurate flow of information about important drug safety issues.

– Doesn't some Dept. Do this now? FDA?

O

# ASSEMBLY BILL No. 72

**Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, Nava, Pavley, and Salinas)**

January 3, 2005

An act to add Division 114 (commencing with Section 130700) to the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 72, as introduced, Frommer. Prescription drugs: manufacturer reporting requirement.

Existing law regulates the labeling, sale, and use of prescription drugs and devices.

This bill would require a prescription drug manufacturer that offers for sale, transfers, or otherwise furnishes prescription drugs to any person or entity in this state to submit a report to the State Department of Health Services of health studies that have been or are being conducted by or on behalf of that manufacturer pertaining to those drugs. The bill would require the report to be consistent with federal laws applicable to information disseminated by drug manufacturers to a state governmental agency.

This bill would authorize the Attorney General to bring civil actions to enforce the reporting requirements and recover civil penalties that may be assessed by the Attorney General under the bill.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. Division 114 (commencing with Section 130700) is added to the Health and Safety Code, to read:

## DIVISION 114. PRESCRIPTION DRUGS

### CHAPTER 1. DRUG MANUFACTURER HEALTH STUDIES REPORTING

130700. (a) Any manufacturer of prescription drugs that offers for sale, transfers, or otherwise furnishes a prescription drug to any person or entity in this state shall submit a report to the State Department of Health Services of health studies that have been or are being conducted by or on behalf of that manufacturer regarding each prescription drug it sells, transfers, or otherwise furnishes to a person or entity in this state.

(b) Subject to subdivision (c), the report shall include all studies pertaining to each prescription drug, whether the results are positive, negative, neutral, or inconclusive.

(c) The report shall be consistent with requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) that apply to the dissemination of information by a drug manufacturer to a state governmental agency.

130705. (a) The Attorney General may bring a civil action to enforce the requirements of Section 130700.

(b) (1) The Attorney General may assess and recover a civil penalty, as specified in paragraph (2), against a drug manufacturer for each finding of a violation of Section 130700 in a civil action brought under this section.

(2) A drug manufacturer that violates Section 130700 is liable for civil penalties of up to twenty–five thousand dollars ($25,000) for each first violation, not less than fifty thousand dollars ($50,000) nor more than one hundred thousand dollars ($100,000) for each second violation, and not less than one hundred fifty thousand dollars ($150,000) nor more than two hundred thousand dollars ($200,000) for each subsequent violation.

(3) Any civil penalty recovered by the Attorney General under this subdivision shall be deposited in the State Treasury.

(c) In any action under this section in which judgment is entered against the defendant, the Attorney General shall be awarded reasonable attorney's fees together with the costs of suit.

O

# ASSEMBLY BILL No. 73

**Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, Nava, Pavley, and Salinas)**

January 3, 2005

An act to add Section 14982 to the Government Code, and to add Article 5 (commencing with Section 110242) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 73, as introduced, Frommer. Prescription drugs: importation: procurement.

(1) Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

Existing law, the Pharmacy Law, provides that any pharmacy located outside of this state that delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state is considered a nonresident pharmacy and requires a nonresident pharmacy to register with the California State Board of Pharmacy and comply with all lawful directions of, and requests for information from, the state in which it is a resident.

Existing federal law requires any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is imported or offered for import into the United States to register with the federal Secretary of Health and Human Services, report a list of each drug introduced for

commercial distribution, and provide required information and statements.

This bill would establish the California Rx Prescription Drug Web Site Program. The bill would require the State Department of Health Services to administer the program and establish a Web site on or before July 1, 2006, to provide information to California residents about options for obtaining prescription drugs at affordable prices. The bill would require that the Web site, at a minimum, provide information about, and establish electronic links to, certain federal, state, and pharmaceutical programs, pharmacies that are located in Canada, England, and Ireland and that meet specified requirements, and other Web sites.

This bill would authorize the department to assess a fee on international pharmacies that the department reviews for possible inclusion on the Web site to offset the cost of reviewing those pharmacies. The bill would require the department's Web site to include price comparisons of prescription drugs, including prices charged by licensed pharmacies in the state and international pharmacies that provide mail order service to the United States and whose Web sites are linked to the department's Web site.

(2) Existing law authorizes the Department of General Services to administer a coordinated prescription drug bulk purchasing program under which the department may enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single–source or multisource drugs and obtain from them discounts, rebates, and refunds as permissible under federal law. Existing law requires certain state agencies to participate in the program and authorizes any other state, local, and public agency governmental entity to elect to participate in the program.

This bill would require the department to coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from sources other than those from which the state now purchases, including sources that meet the requirements to be listed on the California Rx Prescription Drug Web site. The bill would require the department, on or before January 1, 2007, to conduct the review and report to the Legislature. The bill would require the report to recommend options to facilitate more cost–effective acquisition of prescription drugs. The bill would authorize the department to establish pilot programs under which purchases of prescription drugs

from international pharmacies would be made at reduced prices for purposes of state departments and agencies.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. The Legislature finds and declares all of the following:

(a) Prescription drugs have become essential for ensuring the health of millions of Californians.

(b) The United States is the largest trade market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand name pharmaceuticals in the world.

(c) Increased spending on prescription drugs is a significant driver of increases in overall health care costs, with spending nationwide on prescription drugs rising over 15 percent each year from 2000 to 2002.

(d) Rising out–of–pocket costs for prescription drugs are placing a growing burden on California consumers, as evidenced by federal government statistics show that in 2002 the increase in consumers' out–of–pocket costs for prescription drugs was greater than the increase in out–of–pocket costs for all other health care expenditures.

(e) The price of brand name drugs is rising faster than the rate of inflation, with a recent study showing that the price of 30 drugs most frequently used by the elderly rose by over four times the rate of inflation in 2003 and that some drugs increased in price by 10 times the rate of inflation in that year.

(f) The rising cost of prescription drugs also places a significant burden on state government, with the cost of providing prescription drugs to Medi–Cal beneficiaries, to inmates of the Department of Corrections, and to other participants in state programs growing in some cases at over 20 percent annually in recent years.

(g) The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford the medication they need to stay healthy, as shown by a study by the RAND Corporation that found that when out–of–pocket payments for prescription drugs doubled, patients with diabetes

and asthma cut back on their use of drugs by over 20 percent and subsequently experienced higher rates of emergency room visits and hospital stays.

(h) The rising cost of prescription drugs places a disproportionate burden on communities of color, as shown in a report from the Center for Studying Health System Change that found that African–Americans are about 75 percent and Latinos about 50 percent more likely than nonminorities to not have purchased a prescription drug in 2001 because of cost issues.

(i) A prescription drug is neither safe nor effective to an individual who cannot afford it.

(j) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

SEC. 2. Section 14982 is added to the Government Code, to read:

14982. (a) The Department of General Services shall coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from sources other than those from which the state now purchases, including sources that meet the requirements of Section 110242 of the Health and Safety Code. State departments to be reviewed shall include, but not be limited to, all of the following:

(1) The State Department of Health Services.

(2) The Managed Risk Medical Insurance Board.

(3) The Department of General Services.

(4) The Department of Corrections.

(5) The California Public Employees' Retirement System (CalPERS).

(b) The Department of General Services shall, on or before January 1, 2007, conduct the review required under subdivision (a) and report its findings based on that review to the Legislature. The report shall recommend options to the Legislature, including conducting pilot programs, to facilitate more cost–effective acquisition of prescription drugs. The recommendations shall include a determination of the need to seek any federal approvals or waivers.

(c) The Department of General Services may establish pilot programs under which purchases of prescription drugs from

international pharmacies are made at reduced prices for purposes of state departments and agencies.

(d) As a condition of implementing any pilot program under this section, the Department of General Services shall seek and obtain all appropriate federal waivers and approvals necessary for the implementation of that pilot program.

SEC. 3. Article 5 (commencing with Section 110242) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California Rx Prescription Drug Web Site Program

110242. (a) The California Rx Prescription Drug Web Site Program is hereby established.

(b) The State Department of Health Services shall administer the program. The purpose of the program shall be to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.

(c) The department shall establish a Web site on or before July 1, 2006, which shall, at a minimum, provide information about, and electronic links to, all of the following:

(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program.

(2) State programs that provide drugs at discounted prices for California residents.

(3) Pharmaceutical manufacturer patient assistance programs that provide free or low–cost prescription drugs to qualifying individuals.

(4) International pharmacies that provide mail order service to the United States and who meet the requirements of paragraph (2) of subdivision (d).

(5) Other Web sites as deemed appropriate by the department that help California residents to safely obtain prescription drugs at affordable prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.

(d) (1) The Web site shall include price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by licensed pharmacies in the

state and by international pharmacies that provide mail order service to the United States and whose Web sites are linked to the department's Web site pursuant to paragraph (2).

(2) The Web site shall provide information about, and establish electronic links to, pharmacies that are located in Canada, England, and Ireland that provide mail order services to the United States and that meet all of the following requirements:

(A) Are licensed by the province or country, as appropriate, in which they are located.

(B) Comply with the requirements of a nonresident pharmacy as specified in Section 4112 of the Business and Professions Code except that for purposes of this section all references to "state" in subdivision (d) of Section 4112 of the Business and Professions Code shall be deemed to refer to the province or other licensing jurisdiction in which the pharmacy is located. Compliance with this subparagraph shall be determined by the department in consultation with the California State Board of Pharmacy.

(C) Require a prescription from a patient's personal physician, who is licensed to practice in the United States.

(D) Require the completion of a relevant medical history profile.

(E) Require a signed patient agreement.

(F) Ship prescription drugs in tamper proof original manufacturer containers to individuals in the United States, unless the consumer requests to receive the drug in a childproof container.

(G) Include a physical address and pharmacy license number on its company Web site.

(H) Do not furnish any of the following:

(i) A controlled substance.

(ii) A biological product, as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262).

(iii) An infused drug, including, a peritoneal dialysis solution.

(iv) An intravenously injected drug.

(v) A drug that is inhaled during surgery.

(vi) A drug that requires refrigeration or cannot be safely shipped by mail.

(vii) More than the prescribed amount of a drug or more than a three–month supply of any drug.

(viii) A drug that the consumer indicates he or she has not previously taken.

(ix) A drug for which there is no equivalent drug approved for sale in the United States by the federal Food and Drug Administration.

(I) Sell only prescription drugs that have been approved for sale in the country in which the pharmacy is located by the agency responsible for ensuring the safety of prescription drugs in that country.

(J) Comply with state law regarding the documentation of the pedigree of prescription drugs.

(K) Does not require a consumer to sign a waiver of liability or a release of liability for a negligent act by the pharmacy.

(L) Maintain a service department to respond to consumer inquiries and provide information to consumers about how they may file complaints with the provincial or other applicable licensing authority.

(M) Ensure that all physicians, pharmacists, and technicians in its employ are properly licensed and their licenses are in good standing.

(N) Comply with all personal health and medical information privacy laws applicable to pharmacies located in California.

(O) Any other requirement established by the department to ensure the safety, accessibility, and affordability of prescription drugs.

(3) A pharmacy that seeks to be linked to the department's Web site pursuant to paragraph (2) shall apply to the department. The department may enter into a contract with a pharmacy that it determines meets the requirements of paragraph (2). A contract may be renewed annually upon payment of the fee specified in paragraph (5) provided that the pharmacy continues to comply with the requirements of paragraph (2).

(4) The department may terminate a contract with, and delete an electronic link to, or information about, a pharmacy that the department determines no longer complies with the requirements of paragraph (2). The department shall review within 30 business days any information that it receives regarding a pharmacy's compliance with the requirements of paragraph (2) and shall determine whether the information constitutes grounds for removal of the pharmacy from the Web site.

(5) The department may assess a fee on international pharmacies that the department reviews pursuant to paragraph (2) to offset the cost of reviewing those pharmacies.

(e) The department shall ensure that the Web site established pursuant to this section is coordinated with, and does not duplicate, other Web sites that provide information about prescription drug options and costs.

(f) Any information, including the identity of an international pharmacy, to be posted on the Web site shall first be approved by professional staff of the department before it is posted.

(g) The department shall include on the Web site a notice that informs consumers about state and federal laws governing the importation of prescription drugs and the federal Food and Drug Administration's policy governing personal importation. The notice shall also inform consumers that a pharmacy linked to the Web site is licensed in the country in which it is located and that the department has the right to remove a pharmacy from the Web site if it violates the requirements of paragraph (2) of subdivision (d) or the terms of any agreement between the department and the pharmacy. In addition, the notice shall include a statement that the state accepts no legal liability with respect to any product offered or pharmaceutical services provided by a pharmacy linked to the Web site.

O

# ASSEMBLY BILL No. 74

**Introduced by Assembly Members Gordon and Frommer**

January 3, 2005

An act to add Article 5 (commencing with Section 110243) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 74, as introduced, Gordon. California Rx Prescription Drug Hotline.

Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

This bill would require the department to establish the California Rx Prescription Drug Hotline, on or before July 1, 2006, to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices. The bill would establish a maximum cost per call to the hotline and require the hotline to provide specific information.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. The Legislature finds and declares all of the following:

(a) Prescription drugs have become essential for ensuring the health of millions of Californians.

(b) Increased spending on prescription drugs is a significant driver of increases in overall health care costs.

(c) Rising out–of–pocket costs for prescription drugs are placing a growing burden on California consumers, as federal government statistics show that in 2002 the increase in consumers' out–of–pocket costs for prescription drugs was greater than the increase in out–of–pocket costs for all other health care expenditures

(d) The price of brand name drugs is rising faster than the rate of inflation, with a recent study showing that the price of 30 drugs most frequently used by the elderly rose by over four times the rate of inflation in 2003 and that some drugs increased in price by 10 times the rate of inflation in that period.

(e) The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford the medication they need to stay healthy.

(f) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

SEC. 2. Article 5 (commencing with Section 110243) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California Rx Precription Drug Hotline

110243. (a)The State Department of Health Services shall establish the California Rx Prescription Drug Hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

(b) The department shall establish a low–cost 1–900 telephone number on or before July 1, 2006. Callers shall be provided information about options for obtaining prescription drugs at affordable prices. The cost per call to the hotline shall not exceed 50 cents ($0.50) and the hotline shall, at a minimum, provide information about all of the following:

(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program and the Medicare Prescription Drug Discount and Transitional Assistance Program.

(2) State programs that provide drugs at discounted prices for California residents.

(3) Federal programs that provide drugs at discounted prices for United States residents.

(4) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

(5) Other informational resources as deemed appropriate by the department that help California residents to safely obtain prescription drugs at affordable prices, including, but not limited to, both of the following:

(A) Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government.

(B) Telephone numbers and Web sites of health plans and health insurers regarding their prescription drug formularies.

(6) Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by all of the following:

(A) Licensed pharmacies in the state.

(B) Licensed pharmacies in other states.

(C) Pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.

(c) The department shall ensure that the hotline established pursuant to this section is coordinated with and does not duplicate other state funded programs and services that provide information about prescription drug options and costs.

(d) Any information provided via the hotline shall first be approved by professional staff of the department.

O

# ASSEMBLY BILL No. 75

**Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, Nava, Pavley, and Salinas)**

January 3, 2005

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to prescription drugs, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 75, as introduced, Frommer. Pharmaceutical assistance program.

Under existing law, the State Department of Health Services administers the Medi–Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Plus State Pharmacy Assistance Program, to be administered by the department. The bill would authorize the department to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under the program. The bill would establish eligibility criteria and application procedures for California residents to participate in the program.

The bill would establish the California Rx Plus Program Fund, as a continuously appropriated fund, into which all payments received

under the program would be deposited, with this fund to be used for the purpose of implementing the program.

The bill would transfer $5,000,000 from the General Fund to the California Rx Plus Program Fund, thus constituting an appropriation.

Vote: 2/3. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. Division 112 (commencing with Section 130500) is added to the Health and Safety Code, to read:

## DIVISION 112. CALIFORNIA RX PLUS STATE PHARMACY ASSISTANCE PROGRAM

### CHAPTER 1. GENERAL PROVISIONS

130500. (a) This division shall be known, and may be cited, as the California Rx Plus State Pharmacy Assistance Program.

(b) For purposes of this division, the following definitions apply:

(1) "Department" means the State Department of Health Services.

(2) "Fund" means the California Rx Plus Program Fund.

(3) "Program" means the California Rx Plus State Pharmacy Assistance Program.

(4) (A) "Qualified resident" means a resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines, as updated periodically in the Federal Register by the United States Department of Health and Human Services under the authority of Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902(2)).

(B) "Qualified resident" also means a resident of the state whose family incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of family income or whose total unreimbursed medical expenses equal 15 percent or more of family income.

(C) For purposes of this paragraph, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.

130501. There is hereby established in the State Department of Health Services, the California Rx Plus State Pharmacy Assistance Program.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCEDURES

130505. (a) To be eligible for the program, an individual shall be a qualified resident, as defined in paragraph (4) of subdivision (b) of Section 130500 and shall not have outpatient prescription drug coverage paid for in whole or in part by the Medi–Cal program or the Healthy Families Program.

(b) An individual enrolled in Medicare may participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare.

130506. (a) The department shall establish application forms and procedures for enrollment in the program.

(b) In assessing the income requirement for program eligibility, the department shall use the income information reported on the application and shall not require additional documentation.

(c) Upon determination of eligibility, the department shall mail the qualified resident a California Rx Plus Discount Card.

CHAPTER 3. ADMINISTRATION AND SCOPE

130515. The department shall conduct an outreach program to inform California residents of their opportunity to participate in the California Rx Plus State Pharmacy Assistance Program. The department shall coordinate outreach activities with the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program.

130516. (a) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program.

(b) Any drug manufacturer may participate in the program.

130517. (a) The amount a program participant pays for a drug through the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the

specific drug or an average discount for a group of drugs or all drugs covered by the program.

(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the drug's manufacturer and the state's share of the discount.

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

130518. (a) The department shall negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program.

(b) Upon receipt of a determination from the federal Centers for Medicare and Medicaid Services that the program is a state pharmaceutical assistance program as provided in Section 130522, the department shall seek to contract for drug rebates that result in a net price lower than the Medicaid best price for drugs covered by the program.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.

(d) No less than 95 percent of the drug rebates negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by participants in the program.

130519. (a) To the extent permitted by federal law, and subject to any necessary federal approvals or waivers, the department may require prior authorization in the Medi–Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) for any drug of a manufacturer that does not agree to provide rebates to the department for prescription drugs purchased under this division.

(b) The names of manufacturers that do and do not enter into rebate agreements with the department pursuant to this division shall be public information and shall be released to the public.

130520. Contracts entered into for purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. Contracts with pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

130521. (a) The department shall execute agreements with drug manufacturer patient assistance programs to provide a

single point of entry for eligibility determination and claims processing for drugs available through those programs.

(b) The department shall develop a system to provide a participant under this division with the best discounts on prescription drugs that are available to the participant through this program or through a drug manufacturer patient assistance program.

(c) (1) The department may require an applicant to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.

(2) The department shall not require an applicant to participate in a drug manufacturer patient assistance program or to disclose information that would determine the applicant's eligibility to participate in a drug manufacturer patient assistance program in order to participate in the program established pursuant to this division.

(d) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the department shall require drug manufacturers to provide the department annually with all of the following information:

(1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(2) The total number of prescriptions or 30–day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(e) The California Rx Plus Discount Card issued pursuant to subdivision (c) of Section 130506 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a health benefit card.

130522. The department shall seek a determination from the federal Centers for Medicare and Medicaid Services that the program established pursuant to this division complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) and that discounts provided under the program are exempt from the Medicaid best price requirement.

130523. (a) The department shall deposit all payments the department receives pursuant to this division into the California Rx Plus Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, the fund is hereby continuously appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130517 and for defraying the costs of administering this division. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

(c) Notwithstanding Section 16305.7 of the Government Code, the fund shall also contain any interest accrued on moneys in the fund.

SEC. 2. The sum of five million dollars ($5,000,000) is hereby transfered from the General Fund to the California Rx Plus Program Fund, to fund the cost of implementing the California Rx Plus State Pharmacy Assistance Program established pursuant to Division 112 (commencing with Section 130500) of the Health and Safety Code.

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# ASSEMBLY BILL No. 76

**Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, Nava, and Pavley)**

January 3, 2005

An act to amend Section 12803 of, to add Part 5.4 (commencing with Section 14570) to, and to repeal Chapter 12 (commencing with Section 14977) of Part 5.5 of, Division 3 of Title 1 of, the Government Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 76, as introduced, Frommer. Office of Pharmaceutical Purchasing.

Existing law authorizes the Department of General Services to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. Existing law requires 4 state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. Existing law grants the Department of General Services authority with respect to contracting with a pharmaceutical benefits manager or other entity and exploring additional strategies for managing drug costs.

This bill would repeal these provisions. The bill would instead establish within the California Health and Human Services Agency the Office of Pharmaceutical Purchasing with authority and duties to purchase prescription drugs for state agencies similar to that granted to the Department of General Services under the above-described

provisions. The bill would also, however, require the office to be the purchasing agent for additional state entities and the bill would authorize the office to conduct specified activites in order to negotiate the lowest prices possible for prescription drugs. The bill would require the office, on or before February 1, 2007, to submit a report containing specified information to certain committees of the Legislature regarding the program.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. Section 12803 of the Government Code is amended to read:

12803. (a) The California Health and Human Services Agency consists of the following departments: Health Services; Mental Health; Developmental Services; Social Services; Alcohol and Drug Abuse; Aging; Rehabilitation; and Community Services and Development.

(b) The agency also includes the Office of Statewide Health Planning and Development and the State Council on Developmental Disabilities.

(c) The Department of Child Support Services is hereby created within the agency commencing January 1, 2000, and shall be the single organizational unit designated as the state's Title IV-D agency with the responsibility for administering the state plan and providing services relating to the establishment of paternity or the establishment, modification, or enforcement of child support obligations as required by Section 654 of Title 42 of the United States Code. State plan functions shall be performed by other agencies as required by law, by delegation of the department, or by cooperative agreements.

*(d) The Office of Pharmaceutical Purchasing is hereby established within the agency and shall purchase prescription drugs for state agencies pursuant to Part 5.4 (commencing with Section 14570).*

SEC. 2. Part 5.4 (commencing with Section 14570) is added to Division 3 of Title 1 of the Government Code, to read:

PART 5.4. OFFICE OF PHARMACEUTICAL PURCHASING

14570. As used in this part, "office" means the Office of Pharmaceutical Purchasing within the California Health and Human Services Agency.

14571. (a) Notwithstanding any other provision of law, the office may enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. The office may obtain from those manufacturers and suppliers, discounts, rebates, or refunds based on quantities purchased insofar, as permissible under federal law. Contracts entered into pursuant to this part may include price discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices.

(b) Contracts under this part shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(c) To the extent permitted by federal law, and subject to any necessary federal approvals or waivers, the State Department of Health Services may require prior authorization in the Medi-Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) for any drug of a manufacturer that does not agree to provide rebates to the office for prescription drugs purchased under this part.

14572. (a) The office shall be the purchasing agent for prescription drugs for all of the following state entities:

(1) State Department of Health Services.
(2) Department of Corrections.
(3) State Department of Mental Health.
(4) Department of the Youth Authority.
(5) State Department of Developmental Services.
(6) Department of Veterans Affairs.
(7) California State University.
(8) Any other state agency as directed by the Governor.

(b) Any state, district, county, city, municipal, or public agency governmental entity, other than a state entity specified in subdivision (a), may elect to participate in the coordinated purchasing program.

14573. (a) In order to negotiate the lowest prices possible for prescription drugs for purposes of this part, the office may do all of the following:

(1) Establish a formulary or formularies for state programs in consultation with the affected agencies.

(2) Pursue all opportunities for the state to achieve savings through the federal 340B program, as established under Section 340B of the Public Health Service Act (42 U.S.C. Sec. 256b), including the development of cooperative agreements with entities covered under the 340B program that increase access to 340B program prices for individuals receiving presciption drugs through programs in departments described in Section 14572.

(3) Develop an outreach program to ensure that hospitals, clinics, and other eligible entities participate in the program authorized under Section 340B of the Public Health Service Act (42 U.S.C. Sec. 256b).

(b) The office, in consultation with the agencies listed in subdivision (a) of Section 14572, may investigate and implement other options and strategies to achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

14574. The office may appoint and contract with a pharmaceutical benefits manager or other entity for purposes of the prescription drugs purchased under this part. The pharmaceutical benefits manager or other entity may do all of the following:

(a) Negotiate price discounts, rebates, or other options that achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

(b) Purchase prescription drugs for participating state, district, county, or municipal governmental entities.

(c) Act as a consultant to the office.

14575. The department may explore additional strategies for managing the increasing costs of prescription drugs, including, but not limited to, all of the following:

(a) Coordinating programs offered by pharmaceutical manufacturers that provide prescription drugs for free or at reduced prices.

(b) Studying the feasibility and appropriateness of including in the bulk purchasing programs entities in the private sector, including employers, providers, and individual consumers.

(c) Implementing other strategies, as permitted under state and federal law, aimed at managing escalating prescription drug prices.

14576. On or before February 1, 2007, the office shall submit a report to the appropriate policy and fiscal committees of the Legislature on activities that have been or will be undertaken pursuant to this part. The report shall include, but not be limited to, all of the following:

(a) The number and a description of contracts entered into with manufacturers and suppliers of drugs pursuant to Section 14571, including any discounts, rebates, or refunds obtained.

(b) The number and a description of entities that elect to participate in the coordinated purchasing program pursuant to subdivision (b) of Section 14572.

(c) Other options and strategies that have been or will be implemented pursuant to Sections 14573 and 14575.

(d) Estimated costs and savings attributable to activities that have been or will be undertaken pursuant to this part.

SEC. 3. Chapter 12 (commencing with Section 14977) of Part 5.5 of Division 3 of Title 1 of the Government Code is repealed.

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# ASSEMBLY BILL No. 78

**Introduced by Assembly Members Pavley and Bass**
**(Coauthors: Assembly Members Chan, Evans, Frommer, Gordon, and Koretz)**

January 3, 2005

An act to add Division 113 (commencing with Section 150000) to the Health and Safety Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 78, as introduced, Pavley. Pharmacy benefits management.

Existing law provides for the regulation of health care benefits.

This bill would define the term "pharmacy benefits management" as the administration or management of prescription drug benefits. The bill would also define the term "pharmacy benefits manager" as an entity that performs pharmacy benefits management. The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers, including specified information about the pharmacy benefit manager's revenues and its drug formularies, and to make specified disclosures to the public upon request. The bill would also establish certain standards and requirements with regard to pharmacy benefits management contracts and the provision of certain drugs. The bill would impose certain requirements on the membership of a pharmacy and therapeutics committee for a pharmacy benefits manager. The bill would also require a pharmacy benefits manager to meet certain conditions before substituting a prescribed medication.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. Division 113 (commencing with Section 150000) is added to the Health and Safety Code, to read:

DIVISION 113. PHARMACY BENEFITS MANAGEMENT

150000. For purposes of this division, the following definitions shall apply:

(a) "Labeler" means any person who receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration under Section 207.20 of Title 21 of the Code of Federal Regulations.

(b) "Pharmacy benefits management" is the administration or management of prescription drug benefits. Pharmacy benefits management shall include all of the following: the procurement of prescription drugs at a negotiated rate for dispensation within this state, the processing of prescription drug claims, and the administration of payments related to prescription drug claims.

(c) "Pharmacy benefits manager" is any person who performs pharmacy benefits management. The term does not include a health care service plan or health insurer if the health care service plan or health insurer offers or provides pharmacy benefits management services and if those services are offered or provided only to enrollees, subscribers, or insureds who are also covered by health benefits offered or provided by that health care service plan or health insurer, nor does the term include an affiliate, subsidiary, or other related entity of the health care service plan or health insurer that would otherwise qualify as a pharmacy benefits manager, as long as the services offered or provided by the related entity are offered or provided only to enrollees, subscribers, or insureds who are also covered by the health benefits offered or provided by that health care service plan or health insurer.

(d) "Prospective purchaser" is any person to whom a pharmacy benefits manager offers to provide pharmacy benefit management services.

(e) "Purchaser" is any person who enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefit management services.

150001. A pharmacy benefits manager shall disclose to the purchaser in writing all of the following:

(a) The aggregate amount of all rebates and other retrospective utilization discounts that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits specific to the purchaser.

(b) For a specified list of therapeutic classes, the aggregate amount for each therapeutic class of all rebates and other retrospective utilization discounts that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits specific to the purchaser. A therapeutic class shall include at least two drugs.

(c) The nature, type, and amount of all other revenue that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the purchaser. A pharmacy benefits manager shall not be required to disclose the purchase discounts based upon invoiced purchase terms for prescription drugs purchased directly or indirectly from a pharmaceutical manufacturer or labeler for sale and distribution through the mail order pharmacy of the pharmacy benefits manager.

(d) Any prescription drug utilization information related to utilization by the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser.

(e) Any administrative or other fees charged by the pharmacy benefits manager to the purchaser.

(f) Any arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

(g) Any financial arrangements related to the provision of pharmacy benefits management to the purchaser that exist

between the pharmacy benefits manager and any brokers, consultants, consulting companies, or other intermediaries.

150002. A pharmacy benefits manager shall disclose to a prospective purchaser in writing all of the following:

(a) The aggregate amount of all rebates and other retrospective utilization discounts that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits manager.

(b) For a specified list of therapeutic classes, the aggregate amount for each therapeutic class of all rebates and other retrospective utilization discounts that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits specific to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits manager. A therapeutic class shall include at least two drugs.

(c) The nature, type, and amount of all other revenue that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits manager. A pharmacy benefits manager shall not be required to disclose the purchase discounts based upon invoiced purchase terms for prescription drugs purchased directly or indirectly from a pharmaceutical manufacturer or labeler for sale and distribution through the mail order pharmacy of the pharmacy benefits manager.

(d) Any administrative or other fees charged by the pharmacy benefits manager to the prospective purchaser.

(e) Any arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

150003. (a) A pharmacy benefits manager shall provide the information described in Section 150001 no less frequently than on a quarterly basis.

(b) Except for utilization information, a pharmacy benefits manager need not make the disclosures required in Sections 150001 and 150002 unless and until the purchaser or prospective purchaser agrees in writing to maintain as confidential any proprietary information. That agreement may provide for equitable and legal remedies in the event of a violation of the agreement. That agreement may also include persons or entities with whom the purchaser or prospective purchaser contracts to provide consultation regarding pharmacy services. Proprietary information includes trade secrets, and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers and personnel held by a pharmacy benefits manager and used for its business purposes.

150004. A pharmacy benefits manager may not execute a contract for the provision of pharmacy benefits management services that fails to address the following items:

(a) The amount of the total revenues, rebates, and discounts identified in subdivisions (a), (b), and (c) of Section 150001 and subdivisions (a), (b), and (c) of Section 150002 that shall be passed on to the purchaser.

(b) The disclosure or sale of enrollee utilization data by the pharmacy benefits manager to any person or entity other than the purchaser.

(c) Any administrative or other fees charged by the pharmacy benefits manager to the purchaser.

(d) Conditions under which an audit will be conducted of the contract for pharmacy benefits management services, who will conduct the audit, and who will pay for the audit.

(e) Any revenues, rebates, or discounts received by the pharmacy benefits manager directly or indirectly from entities other than manufacturers and labelers that are related to the services to be provided to the purchaser.

(f) The process for development of formularies and notification of changes to formularies, and approval of those changes by the purchaser, provided that the pharmacy benefits manager meets the requirements of Sections 150005, 150006, and 150007.

(g) Whether there is a difference between the price paid to a retail pharmacy and the amount that will be billed to the purchaser for prescription drugs.

150005. (a) All members of a pharmacy and therapeutics committee for a pharmacy benefits manager shall be physicians, pharmacists, academics, or other health care professionals, and a majority of committee members shall not be employed by the pharmacy benefits manager.

(b) A pharmacy and therapeutics committee member shall not be an officer, employee, director, or agent of, or any person who has financial interest in, other than ownership of stock from open market purchases of less than a nominal amount of the outstanding stock of, pharmaceutical companies.

150006. (a) Except as provided in subdivision (b), any request from a pharmacy benefits manager to a prescriber for authorization to substitute a medication shall include all of the following disclosures:

(1) The cost savings for the purchaser, if any, that are a result of the medication substitution.

(2) The difference, if any, in copayments or other out-of-pocket costs paid by the patient in order to obtain the medication.

(3) The existence of additional payments received by the pharmacy benefits manager that are not reflected in the cost savings to the purchaser.

(4) The circumstances, if any, under which the currently prescribed medication will be covered.

(5) The circumstances and extent to which, if any, related health care costs arising from the medication substitution will be compensated.

(6) Any known differences in potential effects on a patient's health and safety, including side effects.

(b) A pharmacy benefits manager shall not be required to make the disclosures required by subdivision (a) under any of the following instances:

(1) The substitution is from a brand drug to a generic or chemical equivalent in accordance with applicable state law.

(2) The medication substitution is initiated for patient safety reasons.

(3) The currently prescribed medication is no longer available in the market.

(4) The substitution is initiated pursuant to a drug utilization review.

(5) The substitution is required for coverage reasons where the prescribed drug is not covered by the patient's formulary or plan.

(c) A pharmacy benefits manager shall record the name and title of the prescriber, or the person other than the prescriber, authorizing the medication substitution if the authorization is given verbally.

(d) The pharmacy benefits manager shall not substitute a medication for a currently prescribed medication unless the pharmacy benefits manager communicates with the patient to provide that patient or their representative the following information:

(1) The proposed medication and the currently prescribed medication.

(2) The difference in copayments or other out-of-pocket costs paid by the patient, if any.

(3) Potential side effects of the medication substitution.

(4) The circumstances, if any, under which the currently prescribed medication will be covered.

(5) The circumstances and the extent to which, if any, health care costs related to the medication substitution will be compensated.

(6) Notification that the patient may decline the medication substitution if the currently prescribed drug remains on the patient's formulary, and the patient is willing to pay any difference in the copayment amount.

(7) A toll-free telephone number to communicate with the pharmacy benefits manager.

(e) The pharmacy benefits manager shall cancel and reverse the medication substitution upon written or verbal instructions from a prescriber or the patient. The pharmacy benefits manager shall not be required to cancel and reverse the medication substitution if the prescribed drug is no longer on the purchaser's formulary or the patient is unwilling to pay a higher copayment or other cost associated with the prescribed drug.

(f) The pharmacy benefits manager shall maintain a toll-free telephone number during normal business hours for a minimum

of eight hours per day Monday through Friday for prescribers and patients.

(g) The pharmacy benefits manager shall not charge the individual any additional copayments or fees related to the replacement medication.

150007. A pharmacy benefits manager shall monitor the health effects on patients of medication substitutions requested by the pharmacy benefits manager. The pharmacy benefits manager shall, on a quarterly basis, report to his or her Pharmacy and Therapeutics Committee the results of the monitoring. This report shall include all patient and prescriber communications received by the pharmacy benefits manager that concern the efficacy or health effects of the medication substitutions.

150008. All disclosures made pursuant to this division shall comply with the privacy standards of the federal Health Insurance Portability and Accountability Act.

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# ASSEMBLY BILL No. 95

**Introduced by Assembly Member Koretz**
**(Coauthors: Assembly Members Bass, Chan, Evans, and Pavley)**

January 10, 2005

An act to add Division 112 (commencing with Section 140000) to the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 95, as introduced, Koretz. Prescription drugs: Medi–Cal.

Existing law provides for the Medi–Cal program, which is administered by the State Department of Health Services, pursuant to which medical benefits are provided to public assistance recipients and certain other low–income persons.

Existing law requires the department to administer the AIDS Drug Assistance Program. Under existing law, the department subsidizes the cost of drugs for AIDS for persons who do not have private health coverage, are not eligible for Medi–Cal, or cannot afford to purchase the drug privately.

This bill would establish a program that would require manufacturers of drugs for life-threatening chronic conditions that are on the list for Medi–Cal or the AIDS Drugs Assistance Program to pay the department a rebate equal to the costs of marketing that drug. The bill also would require these manufacturers to disclose to the department all costs incurred in the marketing of the drugs to consumers and physicians.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

SECTION 1. Division 112 (commencing with Section 140000) is added to the Health and Safety Code, to read:

## DIVISION 112. PHARMACEUTICAL MARKETING EXPENDITURE REBATE

140000. (a) The Legislature finds and declares all of the following:

(1) The cost of drugs in our country has been the subject of intense debate for several years. While the pharmaceutical industry is continually one of the most profitable, drug spending continues to increase dramatically year after year.

(2) The reasoning of the pharmaceutical industry has been that the high cost of drugs is a result of the industry's enormous research and development effort, both in terms of paying back the research and development costs once the federal Food and Drug Administration approves a drug and investing in future research and development.

(3) Recent studies have discerned that marketing costs exceed research and development costs, on average, by more than two to one. A study based on Securities and Exchange Commission filings indicates that companies' marketing costs range from 15 percent to 42 percent while research and development costs range from 6 percent to 19 percent and, in all cases, the marketing costs significantly exceeded the research and development costs.

(4) Pharmaceutical companies devote 84 percent of their marketing costs to physicians, including sales representatives, free samples, gifts, trips, and ads in medical journals.

(b) The Legislature further finds and declares that the high cost of drugs for people with life-threatening conditions imperils their condition for several reasons:

(1) Many patients simply cannot afford the drug.

(2) The state is limited as to how much it can spend purchasing or subsidizing these critical drugs, especially as the state faces an immediate multibillion dollar deficit and the threat of deficits for at least the next few years.

(3) Budgets for Medi–Cal and targeted drug programs like the AIDS Drug Assistance Program are escalating, in large part, because the drug prices are escalating.

(4) Third–party payers often refuse to approve treatment requests using many of these drugs because of the high costs.

(5) Some marketing expenses are used for inappropriate advertising that does a disservice to persons with life–threatening illnesses as well as persons who may be at risk of life–threatening illnesses. Advertising often leaves a Madison Avenue–style impression that a particular drug is a cure when it is actually a treatment.

(c) Therefore, it is the intent of the Legislature to prohibit the State of California from paying for pharmaceutical manufacturers' costs related to marketing those drugs that are prescribed for life–threatening chronic conditions, except to the extent that those costs are associated with the necessary and appropriate education of patients and physicians.

140005. (a) Manufacturers of drugs for life–threatening chronic conditions that are on the list for Medi–Cal or the AIDS Drugs Assistance Program shall pay the department a rebate equal to the costs of marketing that drug. For purposes of this section, marketing means any cost associated with direct–to–consumer advertising, cash payments to physicians of any kind, gifts to physicians that are not directly related to the benefit of the patient or the practice of the physician related to the drug, travel, meals, or lodging for the physician unless they are associated with legitimate physician education and then only if the costs are reasonable and in pursuit of legitimate physician education, and any other cost that is not directly related to the benefit of the patient or the practice of the physician related to the drug. For purposes of this section, "life–threatening chronic condition" means a condition or disease that requires specialized medical care over a prolonged period of time and will result in death within five years without an appropriate drug regimen.

(b) To determine the amount appropriate in subdivision (a), the department shall require each drug manufacturer to disclose to the department all costs incurred in the marketing of the drug to consumers and physicians.

(1) If the manufacturer complies with the disclosure requirement, the department shall agree to a marketing rebate

that allows the manufacturer to retain up to 10 percent of its marketing costs.

(2) If the manufacturer does not comply with the disclosure requirement, the department shall agree to a marketing rebate that is equal to at least 25 percent of the Public Health Service price of the drug.

(c) The marketing rebate negotiated between the manufacturers and the department pursuant to subdivision (a) shall be in addition to any rebate that would be applicable to the drug under Section 1927(c) of the federal Social Security Act (42 U.S.C. Sec. 1396r–8(c)) and any supplemental rebate otherwise negotiated with the department.

(d) Drugs may be removed from the Medi–Cal or AIDS Drug Assistance Program list for failure to pay the rebate required by subdivision (a), unless the department determines that removal of the drug from the list would cause substantial medical hardship to beneficiaries.

(e) The marketing rebate provided for in this section shall be used to supplement, not supplant, any rebate pursuant to other provisions of state or federal law.

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AMENDED IN SENATE JANUARY 6, 2005

# SENATE BILL No. 19

**Introduced by Senator Ortiz**
***(Principal coauthor: Senator Poochigian)***

December 6, 2004

An act to add Division ~~113~~ *112* (commencing with Section 130600) to the Health and Safety Code, relating to ~~prescription drugs~~ *pharmacy assistance* , and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 19, as amended, Ortiz. California Rx Program.

Under existing law, the State Department of Health Services administers the Medi–Cal program, and is authorized, among other things, to enter ~~in to~~ *into* contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufactures are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California ~~Rx Program, to be administered by~~ *Pharmacy Assistance Program (Cal Rx) under the oversight of* the department. The bill would authorize the department to *implement and administer Cal Rx through a contract with a 3rd–party vendor or utilizing existing health care service provider enrollment and payment mechanisms. The bill would require the department or 3rd–party vendor to attempt to* negotiate drug rebate agreements *for Cal Rx* with drug manufacturers ~~to provide for program drug discounts~~. The bill would authorize any licensed pharmacy ~~or~~ *and any* drug manufacturer , *as defined,* to provide services under ~~the program~~ *Cal Rx* . The bill would establish eligibility criteria and application procedures for California residents to participate in ~~the program~~ *Cal Rx. The application process would*

*require an applicant to attest to information provided under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program. The bill would authorize the department to terminate the program if any one of 3 determinations are made .*

The bill would establish the California ~~Rx~~ *State Pharmacy Assistance* Program Fund ~~, as a continuously appropriated fund,~~ into which all payments ~~directly~~ received under ~~the program~~ *Cal Rx* would be deposited. *The bill would continuously appropriate the fund to the department for purposes of Cal Rx.*

~~The bill would appropriate $3,000,000 from the State Treasury to the department to fund staff and contract costs for the program.~~

~~The Pharmacy Law is administered by the California State Board of Pharmacy in the Department of Consumer Affairs.~~

~~This bill would require the Department of Consumer Affairs to implement, as a part of the California Rx Program that would be established under the bill, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering prescription drug costs.~~

*The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.*

*This bill would provide that no reimbursement is required by this act for a specified reason.*

Vote: ⅔. Appropriation: yes. Fiscal committee: yes. State-mandated local program: ~~no~~.

*The people of the State of California do enact as follows:*

~~SECTION 1. Division 113 (commencing with Section 130600) is added to the Health and Safety Code, to read:~~

*SECTION 1. Division 112 (commencing with Section 130600) is added to the Health and Safety Code, to read:*

*DIVISION 112. CALIFORNIA STATE PHARMACY ASSISTANCE PROGRAM (CAL RX)*

*CHAPTER 1. GENERAL PROVISIONS*

*130600. This division shall be known, and may be cited, as the California State Pharmacy Assistance Program or Cal Rx.*

*130601. For the purposes of this division, the following definitions shall apply:*

*(a) "Benchmark price" means the price for an individual drug or aggregate price for a group of drugs offered by a manufacturer equal to the lowest commercial price for the individual drug or group of drugs.*

*(b) "Cal Rx" means the California State Pharmacy Assistance Program.*

*(c) "Department" means the State Department of Health Services.*

*(d) "Fund" means the California State Pharmacy Assistance Program Fund.*

*(e) "Inpatient" means a person who has been admitted to a hospital for observation, diagnosis, or treatment and who is expected to remain overnight or longer.*

*(f) (1) "Lowest commercial price" means the lowest purchase price for an individual drug, including all discounts, rebates, or free goods, available to any wholesale or retail commercial class of trade in California.*

*(2) Lowest commercial price excludes purchases by government entities, purchases pursuant to Section 340B of the federal Public Health Services Act (42 U.S.C. Sec. 256b), or nominal prices as defined in federal Medicaid drug rebate agreements.*

*(3) A purchase price provided to an acute care hospital or acute care hospital pharmacy may be excluded if the prescription drug is used exclusively for an inpatient of the hospital.*

*(4) Wholesale or retail commercial class of trade includes distributors, retail pharmacies, pharmacy benefit managers, health maintenance organizations, or any entities that directly or indirectly sell prescription drugs to consumers through licensed retail pharmacies, physician offices, or clinics.*

*(g) "Manufacturer" means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.*

*(h) "Manufacturers rebate" means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.*

*(i) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.*

*(j) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third–party payer program.*

*(k) "Recipient" means a resident that has completed an application and has been determined eligible for Cal Rx.*

*(l) "Resident" means a California resident pursuant to Section 17014 of the Revenue and Taxation Code.*

*(m) "Third–party vendor" means a public or private entity with whom the department contracts pursuant to subdivision (b) of Section 130602, which may include a pharmacy benefit administration or pharmacy benefit management company.*

*130602. (a) There is hereby established the California State Pharmacy Assistance Program or Cal Rx.*

*(b) The department shall provide oversight of Cal Rx. To implement and administer Cal Rx, the department may contract with a third–party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi–Cal program's fiscal intermediary.*

*(c) Any resident may enroll in Cal Rx if determined eligible pursuant to Section 130605.*

### *CHAPTER 2. ELIGIBILITY AND APPLICATION PROCESS*

*130605. (a) To be eligible for Cal Rx, an individual shall meet all of the following requirements at the time of application and reapplication for the program:*

*(1) Be a resident.*

*(2) Have family income, as reported pursuant to Section 130606, that does not exceed 300 percent of the federal poverty*

*guidelines, as revised annually by the United States Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902), as amended.*

*(3) Not have outpatient prescription drug coverage paid for in whole or in part by any of the following:*

*(A) A third–party payer.*

*(B) The Medi–Cal program.*

*(C) The children's health insurance program.*

*(D) The disability medical assistance program.*

*(E) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any other provision of this division to the contrary, an individual enrolled in Medicare may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare.*

*(4) Not have had outpatient prescription drug coverage specified in paragraph (3) during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, unless any of the following applies:*

*(A) The third–party payer that paid all or part of the coverage filed for bankruptcy under the federal bankruptcy laws.*

*(B) The individual is no longer eligible for coverage provided through a retirement plan subject to protection under the Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001), as amended.*

*(C) The individual is no longer eligible for the Medi–Cal program, children's health insurance program, or disability medical assistance program.*

*(b) Application and an annual reapplication for Cal Rx shall be made pursuant to subdivision (d) of Section 130606. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.*

*130606. (a) The department or third–party vendor shall develop an application and reapplication form for the determination of a resident's eligibility for Cal Rx.*

*(b) The application, at a minimum, shall do all of the following:*

*(1) Specify the information that an applicant or the applicant's representative must include in the application.*

*(2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.*

*(3) Include a statement printed in bold letters informing the applicant that knowingly making a false statement is punishable under penalty of perjury.*

*(4) Specify that the application and annual reapplication fee due upon submission of the applicable form is fifteen dollars ($15).*

*(c) In assessing the income requirement for Cal Rx eligibility, the department shall use the income information reported on the application and not require additional documentation.*

*(d) Application and annual reapplication may be made at any pharmacy, physician office, or clinic participating in Cal Rx, through a Web site or call center staffed by trained operators approved by the department, or through the third–party vendor. A pharmacy, physician office, clinic, or third–party vendor completing the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in Cal Rx, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a recipient.*

*(e) The department or third–party vendor shall utilize a secure electronic application process that can be used by a pharmacy, physician office, or clinic, by a Web site, by a call center staffed by trained operators, or through the third–party vendor to enroll applicants in Cal Rx.*

*(f) During normal hours, the department or third–party vendor shall make a determination of eligibility within four hours of receipt by Cal Rx of a completed application. The department or third–party vendor shall mail the recipient an identification card no later than four days after eligibility has been determined.*

*(g) For applications submitted through a pharmacy, the department or third–party vendor may issue a recipient identification number for eligible applicants to the pharmacy for immediate access to Cal Rx.*

*130607. (a) The department or third–party vendor shall attempt to execute agreements with private discount drug programs to provide a single point of entry for eligibility determination and claims processing for drugs available in those private discount drug programs.*

*(b) (1) Private discount drug programs may require an applicant to provide additional information, beyond that required by Cal Rx, to determine the applicant's eligibility for discount drug programs.*

*(2) An applicant shall not be, under any circumstances, required to participate in, or to disclose information that would determine the applicant's eligibility to participate in, private discount drug programs in order to participate in Cal Rx.*

*(3) Notwithstanding paragraph (2), an applicant may voluntarily disclose or provide information that may be necessary to determine eligibility for participation in a private drug discount program.*

*(c) For those drugs available pursuant to subdivision (a), the department or third–party vendor shall develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private discount drug programs.*

*(d) The recipient identification card issued pursuant to subdivision (g) of Section 130606 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.*

### *CHAPTER 3. ADMINISTRATION AND SCOPE*

*130615. (a) To the extent that funds are available, the department shall conduct outreach programs to inform residents about Cal Rx and private drug discount programs available through the single point of entry as specified in subdivisions (a) and (d) of Section 130607. No outreach material shall contain the name or likeness of a drug. The name of the organization sponsoring the material pursuant to subdivision (b) may appear on the material once and in a font no larger than 10 point.*

*(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform*

*residents about Cal Rx. Neither Section 11005 of the Government Code, nor any other law requiring approval by a state officer of a gift, bequest, or donation shall apply to these gifts, bequests, or donations. For purposes of this section, outreach services may include, but shall not be limited to, coordinating and implementing outreach efforts and plans. Outreach materials may include, but shall not be limited to, brochures, pamphlets, fliers, posters, advertisements, and other promotional items.*

*(c) An advertisement provided as a gift, bequest, or donation pursuant to this section shall be exempt from Article 5 (commencing with Section 11080) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.*

*130616. (a) Any pharmacy licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2 of the Business and Professions Code may participate in Cal Rx.*

*(b) Any manufacturer, as defined in subdivision (g) of Section 130601, may participate in Cal Rx.*

*130617. (a) This division shall apply only to prescription drugs dispensed to noninpatient recipients.*

*(b) The amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract rate pursuant to subdivision (c), plus a dispensing fee that shall be negotiated as part of the rate pursuant to subdivision (c), less the applicable manufacturers rebate.*

*(c) The department or third–party vendor may contract with participating pharmacies for a rate other than the pharmacist's usual and customary rate. However, the department must approve the contracted rate of a third–party vendor.*

*(d) The department or third–party vendor shall provide a claims processing system that complies with all of the following requirements:*

*(1) Charges a price that meets the requirements of subdivision (b).*

*(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.*

*(3) Provides a single point of entry for access to private discount drug programs pursuant to Section 130607.*

*(4) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in*

*Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8(g)).*

*(e) The department or third–party vendor shall pay a participating pharmacy the discount provided to recipients pursuant to subdivision (b) by a date that is not later than two weeks after the claim is received.*

*(f) The department or third–party vendor shall develop a program to prevent the occurrence of fraud in Cal Rx.*

*(g) The department or third–party vendor shall develop a mechanism for recipients to report problems or complaints regarding Cal Rx.*

*130618. (a) In order to secure the discount required pursuant to subdivisions (b) and (c) of Section 130617, the department or third–party vendor shall attempt to negotiate drug rebate agreements for Cal Rx with drug manufacturers.*

*(b) Each drug rebate agreement shall do all of the following:*

*(1) Specify which of the manufacturer's drugs are included in the agreement.*

*(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.*

*(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.*

*(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.*

*(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.*

*(6) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.*

*(7) Require the manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).*

*(8) Permit a manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx. Claims information provided to manufacturers shall comply with all federal and state privacy laws that protect a recipient's health information.*

*(c) To obtain the most favorable discounts, the department may limit the number of drugs available within Cal Rx.*

*(d) The entire amount of the drug rebates negotiated pursuant to this section shall go to reducing the cost to Cal Rx recipients of purchasing drugs. The Legislature shall annually appropriate an amount to cover the state's share of the discount provided by this section.*

*(e) The department or third–party vendor may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to this section.*

*(f) Drug rebate contracts negotiated by the third–party vendor shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or Cal Rx recipients.*

*(g) The third–party vendor may directly collect rebates from manufacturers in order to facilitate the payment to pharmacies pursuant to subdivision (e) of Section 130617. The department shall develop a system to prevent diversion of funds collected by the third–party vendor.*

*130619. (a) The department or third–party vendor shall generate a monthly report that, at a minimum, provides all of the following:*

*(1) Drug utilization information.*

*(2) Amounts paid to pharmacies.*

*(3) Amounts of rebates collected from manufacturers.*

*(4) A Summary of the problems or complaints reported regarding Cal Rx.*

*(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.*

*130620. (a) The department or third–party vendor shall deposit all payments received pursuant to Section 130618 into the California State Pharmacy Assistance Program Fund, which is hereby established in the State Treasury.*

*(b) Notwithstanding Section 13340 of the Government Code, moneys in the fund are hereby appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130617 and for defraying the costs of administering Cal Rx. Notwithstanding any other provision of law, no money in the fund*

*is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.*

*130621. The department may hire any staff needed for the implementation and oversight of Cal Rx.*

*130622. The department shall seek and obtain confirmation from the federal Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) and that discounts provided under the program are exempt from Medicaid best price requirements.*

*130623. (a) Contracts and change orders entered into pursuant to this division and any project or systems development notice shall be exempt from all of the following:*

*(1) The competitive bidding requirements of State Administrative Manual Management Memo 03–10.*

*(2) Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.*

*(3) Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of the Government Code.*

*(b) Change orders entered into pursuant to this division shall not require a contract amendment.*

*130624. The department may terminate Cal Rx if the department makes any one of the following determinations:*

*(a) That there are insufficient discounts to participants to make Cal Rx viable.*

*(b) That there are an insufficient number of applicants for Cal Rx.*

*(c) That the department is unable to find a responsible third–party vendor to administer Cal Rx.*

*130625. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this division in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action.*

*SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes*

*the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*

**All matter omitted in this version of the bill appears in the bill as introduced in Senate, December 6, 2004 (JR11)**

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